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Substitute for form 1449A/FTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number	10/630,917
Filing Date	November 20, 2003
First Named Inventor	RUBINSTEIN, Abraham
Group Art Unit	Not yet known
Examiner Name	WEBMAN, E.
Attorney Docket Number	P-4798-US3

Sheet

1

of

Attorney Docket Number

P-4798-US3

U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

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**Examiner
Signature**

Date Considered

10/04

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
Sheet 2 of 5		Application Number	10/630,917
		Filing Date	November 20, 2003
		First Named Inventor	RUBINSTEIN, Abraham
		Group Art Unit	Not yet known
		Examiner Name	WEBMAN, E.
		Attorney Docket Number	P-4798-US3

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AC	BATTAGLIA, E., et al., "Characterization of a New Class of Inhibitors of the Recombinant Human Liver UDP-Glucuronosyltransferase, UGT1*6, Biochimica et Biophysica Acta, 1243 : 9-14 (1995)	<input type="checkbox"/>
	AD	BENET, L.Z., et al., "Importance of Drug Metabolism and Antitransport Processes: A Paradigm Shift in Oral Drug Delivery," Proceedings of the 7th International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, Utah, pp 11-14 (1995)	<input type="checkbox"/>
	AE	BORCHARD, G., et al., "Multifunctional Polymers for Improved Peroral Peptide Drug Absorption," Proceedings of the 7th International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, Utah, pp 7-10, Bai J. P-F., et al. ibid., pp 153-154 (1995).	<input type="checkbox"/>
	AF	CHAO, Y.W. and FLYNN, M., "Oral Delivery of Insulin," Lancet, 23 : 1518-1519 (1989).	<input type="checkbox"/>
	AG	DAMGÉ, C., et al., "New Approach for Oral Administration of Insulin with Polyalkylcyanoacrylate Nanocapsules as Drug Carrier," Diabetes, 37 : 246-251 (1988).	<input type="checkbox"/>
	AH	DANFORTH, JR., E. and MOORE, R.O., "Intestinal Absorption of Insulin in the Rat," Endocrinology, 65 : 118-123 (1959).	<input type="checkbox"/>
	AI	DAPERGOLAS, G. and GREGORIADIS, "Hypoglycaemic Effect of Liposome-Entrapped Insulin Administered Intragastrically into Rats," Lancet, 2 : 824-827 (1976).	<input type="checkbox"/>
	AJ	Eudragit® RL Data Sheet (Info RL-3/e). No date given.	<input type="checkbox"/>
	AK	Eudragit® RL/RS Standards Sheet (Info RL/RS-7/e). No date given.	<input type="checkbox"/>
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	AN	Eudragit® RL and RS Application in the Production of Pharmaceutical Preparations Prospectus (Info RL/RS-1/e). No date given	<input type="checkbox"/>

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				Examiner Name		WEBMAN, E	
Sheet	3	of	5	Attorney Docket Number		P-4798-US3 NOV 24 2003	

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J	AO	FAHR, A., "Cyclosporin Clinical Pharmacokinetics," Clin. Pharmacokinet., 24(6) : 472-495 (1993)	<input type="checkbox"/>
	AP	GEARY, R.S. and SCHLAMEUS, H.W., "Vancomycin and Insulin Used as Models for Oral Delivery of Peptides," J. Controlled Release, 23 : 65-74 (1993)	<input type="checkbox"/>
	AQ	GORIYA, Y., et al., "Blood Glucose Control and Insulin Clearance in Unrestrained Diabetic Dogs Portally Infused with a Portable Insulin Delivery System," Diabetologia, 19 : 452-457 (1980)	<input type="checkbox"/>
	AR	HOCHMAN, J.H., et al., "In vitro and In Vivo Analysis of the Mechanism of Absorption Enhancement by Palmitoylcarnitine," J. Pharm. and Exp. Therap., 269 (2) : 813-822 (1994)	<input type="checkbox"/>
	AS	HOCHMAN, J. and ARTURSSON, P., "Mechanisms of Absorption Enhancement and Tight Junction Regulation," J. Controlled Release, 29 : 256-267 (1994)	<input type="checkbox"/>
	AT	HONESCH, H., et al., "Cytochrome P-450 and Drug Metabolism in Intestinal Villous and Crypt Cells of Rats: Effect of Dietary Iron," Biochem and Biophys. Res. Comm., 65(1) : 399-406 (1975)	<input type="checkbox"/>
	AU	KIDRON, M., et al., "The Absorption of Insulin From Various Regions of the Rat Intestine," Life Science, 31 (25) : 2837-2841 (1982).	<input type="checkbox"/>
	AV	KRAELING, M.E.K. and RITSCHER, W.A., "Development of a Colonic Release Capsule Dosage Form and the Absorption of Insulin," Meth Find Exp. Clin. Pharmacol., 14(3) : 199-209 (1992)	<input type="checkbox"/>
	AW	LEE, V.H.L., et al., "Oral Route of Peptide and Protein Drug Delivery," V.H.L. Lee (Ed.) : Peptide and Protein Drug Delivery, Marcel Dekker, 1991 New York, pp 691-738.	<input type="checkbox"/>
	AX	MORISHITA, M., et al., "Novel Oral Microspheres of Insulin With Protease Inhibitor Protecting From Enzymatic Degradation," Intl. J. Pharmaceutics, 78 : 1-7 (1992).	<input type="checkbox"/>
	AY	MURANISHI, S., "Absorption Enhancers," Critical Reviews in Therapeutic Drug Carrier Systems, 7(1) : 1-34 (1990)	<input type="checkbox"/>
	AZ	OSBORNE, R., et al., "Morphine and Metabolite Behavior After Different Routes of Morphine Administration: Demonstration of the Importance of the Active Metabolite Morphine-6-Glucuronide," Clin. Pharmacol, Ther., 47(1) : 12-19 (1990)	<input type="checkbox"/>

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		Filing Date	November 20, 2003
		First Named Inventor	RUBINSTEIN, Abraham P E
		Group Art Unit	Not yet known
		Examiner Name	WEBMAN, E. NOV 24 2003
		Attorney Docket Number	P-4798-US3
Sheet	4 of 5		

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J	AA2	PATEL, H.M. and RYMAN, B.E., "Oral Administration of Insulin by Encapsulation Within Liposomes," FEBS Letters, 26(1) : 60-63 (1976)	<input type="checkbox"/>
	AB2	PETERS, W.H.M., et al., "Glutathione S-Transferase, Cytochrome P450, and Uridine 5' - Diphosphate-Glucuronosyltransferase in Human Small Intestine and Liver," Gastroenterology, 96 : 783-789 (1989)	<input type="checkbox"/>
	AC2	SAFFRAN, M., et al., "A New Approach to the Oral Administration of Insulin and other Peptide Drugs," Science, 233 : 1081-1084 (1986)	<input type="checkbox"/>
	AD2	SANDERS, L.M., et al., "Prolonged Controlled-Release of Nafarelin, A Luteinizing Hormone-Releasing Hormone Analogue, From Biodegradable Polymeric Implants: Influence of Composition and Molecular Weight of Polymer," J. Pharm. Sci., 75(4) : 356-360 (1986)	<input type="checkbox"/>
	AE2	SANDERS, L.M., et al., "Controlled Delivery of an LHRH Analogue From Biodegradable Injectable Microspheres," J. Controlled Release, 2 : 187-195 (1985).	<input type="checkbox"/>
	AF2	SCHULTE-HERMANN, R. and PARZEFALL, W., "Adaptive Responses of Rat Liver to the Gestagen and Anti-Androgen Cyproterone Acetate and other Inducers. I. Induction of Drug-Metabolizing Enzymes," Chem Biol. Interactions, 31 : 279-286 (1980).	<input type="checkbox"/>
	AG2	TAKAHASHI, K., et al., "Decanoic Acid Induced Enhancement of Rectal Absorption of Hydrophilic Compounds in Rats," Pharmaceutical Res., 11(10) : 1401-1404 (1994)	<input type="checkbox"/>
	AH2	TAKAHASHI, K., et al., "Pharmacokinetics Analysis of the Absorption Enhancing Action of Decanoic Acid and its Derivatives in Rats," Pharm. Res., 11(3) : 388-392 (1994).	<input type="checkbox"/>
	AI2	TOUITOU, E. and RUBINSTEIN, A., "Targeted Enteral Delivery of Insulin to Rat," Intl. J. Pharm., 30 : 95-99 (1986)	<input type="checkbox"/>
	AJ2	VAN HOOGDALAM, E.J., et al., "Intestinal Drug Absorption Enhancement: an Overview," Pharmac. Ther., 44 : 407-443 (1989)	<input type="checkbox"/>
J	AK2	WAHLSTRÖM, A., et al., "Tricyclic Antidepressants Inhibit Opioid.. Receptor Binding in Human Brain and Hepatic Morphine Glucuronidation," Phar. & Toxic., 75 : 23-27 (1994).	<input type="checkbox"/>

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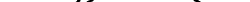
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J g j	AL2	WEINGARTEN, C., et al., "Oral Ingestion of Insulin Liposomes: Effects on the Administration Route," Life Science, 28 : 2747-2752 (1981)	<input type="checkbox"/>
	AM2	ZIV, W., et al., "Absorption of Protein via the Intestinal Wall, Biochem. Pharmacol, 36(7) : 1035-1039 (1987)	<input type="checkbox"/>
	AN2	Database WPI, Week 9530, Derwent Publications Ltd., London, GB; AN 95-228636 & JP, A, 07 138 182 (TOYOBO et al.), 30 May 1995 Abstract.	<input type="checkbox"/>
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